

U.S. Patent Application No. 10/681,352  
Amendment After Final dated December 31, 2007  
Reply to Final Office Action of November 2, 2007

### **REMARKS/ARGUMENTS**

Reconsideration and continued examination of the above-identified application are respectfully requested.

Claims 25-28 are pending. Claim 25 has been editorially amended. Claims 27-28 have been withdrawn. Support for the amendments to the claims can be found, for example, at pages 18-19 and 22-23 of the present application. Therefore, no new questions of patentability should arise nor does the amendment necessitate any further searching on the part of the Examiner. The amendment places the application in condition for allowance. At a minimum, the amendment places the application in a better condition for appeal. Accordingly, no questions of new matter should arise and entry of this amendment is respectfully requested.

### **Claim of Priority**

At page 2 of the Office Action, the Examiner acknowledges receipt of certified copies of the two Japanese priority documents filed on December 28, 2006. The Examiner incorrectly states that applicant's claim for priority is for the date of October 8, 2003. The applicant's claim for priority is for the filing dates of the two Japanese priority documents, April 10, 2001 and September 4, 2001. Correction of the record is respectfully requested.

### **Rejection of Claims 25-26 Under 35 U.S.C. §112, Second Paragraph**

At page 3 of the Office Action, the Examiner states that claims 25-26 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that the phrase "based on the amino acids encoded" in claim 25 is unclear. The Examiner acknowledges

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that it is apparent that a cancer treatment may be determined based on the amino acids encoded, but states that the claim language suggests that the probability of prolonging the cancer patient's survival is based on the amino acids encoded. This rejection is respectfully traversed.

The applicants believe claim 25 would be understood clearly by one skilled in the art. However, to address the Examiner's concerns, by way of this amendment, claim 25 has been amended to specify that the determination of a cancer treatment is based on the amino acids encoded. Accordingly, the applicant respectfully requests the Examiner to withdraw this rejection.

**Rejection of Claims 25-26 Under 35 U.S.C. §103(a) – Davies et al. in view of Lee et al. and further in view of Santamaria et al.**

Beginning at page 4 of the Office Action and continuing to page 7, the Examiner states that claims 25 and 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Davies et al. (J. CLINICAL ONCOLOGY, vol. 19, pp. 1279-87, 2001) in view of Lee et al. (GASTROENTEROLOGY, vol. 111, pp.426-32, 1996) and further in view of Santamaria et al. (U.S. Patent No. 5,972,604). The Examiner states that the mention of chemotherapy treatments in Davies et al. reads on treatment, as defined in the claims. The Examiner also states that Lee et al. draws an association between HLA-DQB1 gene and cancer. The Examiner also states that Lee et al. suggests that individuals most likely to benefit from cancer screening and prevention programs can be targeted and novel strategies for cancer immunoprevention can be developed if the mechanism associating HLA-DQB1 \*0301 with gastric cancer can be identified. The Examiner states that Lee et al. provides motivation for combining the analysis as taught by Davies et al. with the analysis taught by Lee et al. for determining cancer screening and prevention programs developing strategies for cancer immunoprevention. This rejection is respectfully traversed.

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Davies et al. fails to teach or suggest the claimed methods, when viewed alone or in combination with the secondary references cited by the Examiner. Davies et al. shows that GSTT1-negative patients with AML treated with intensively timed chemotherapy have increased treatment-related mortality compared with patients with at least one GSTT1 allele. Davies et al. does not teach or suggest a method for determining treatments for a cancer patient, which involves determining what amino acids are encoded by the recited positions of the HLA DQB1\* gene of the patient, determining what amino acids are encoded by the recited positions of the DRB1\* gene of the patient, and determining what amino acids are encoded by the recited positions of the DPB1\* gene of the patient.

The applicant further submits that Lee et al. and Santamaria et al. do not alone, or in combination, overcome the deficiencies identified in Davies et al. The Examiner states that Lee et al. draws an association between HLA-DQB1 gene and cancer. The applicant notes, however, that Lee et al. merely shows that HLA-DQB1\*301 is more common in Caucasian patients with gastric adenocarcinoma than noncancer controls. Lee et al. does not draw an association between the DPB1\* gene and cancer treatment. In fact, Lee et al. does not teach or even suggest any method for determining treatments for cancer patients. The applicant also notes the Examiner's assertion that Lee et al. discloses the possibility for development of novel strategies for cancer immunoprevention. The applicant points out, however, that cancer immunoprevention is an alternative approach to cancer prevention based on the stimulation of the immune system before tumor onset, while the present claims are directed to determining cancer treatment. Accordingly, the Examiner's reference to Lee et al. for potential developments in cancer prevention does not overcome the above-noted deficiencies in Davies et al.

Accordingly, the applicant respectfully requests the Examiner to withdraw this rejection.

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**CONCLUSION**

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any fees due in connection with the filing of this Amendment, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such extension is requested and should also be charged to our Deposit Account.

Respectfully submitted,



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